AF/1641

Docket No. 25401-25

PATENT

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Bonnie S. Kerner

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	Ib Mendel-Hartvig et al	:	Paper No.:
Serial No.:	09/582,734	:	Group Art Unit: 1641
Filing Date:	October 6, 2000	:	Examiner: G. Counts

For: **Analytical Method Comprising Addition in Two or More Positions and a Device and Test Kit Therefor**

TRANSMITTAL OF REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Submitted herewith in **triplicate** is a Reply Brief in response to the Examiner's Answer mailed December 17, 2004. Also submitted herewith is a Request for Oral Hearing.

Please charge any additional fees required in connection with these filings to Deposit Account No. 04-1133.

Respectfully submitted,

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Bonnie S. Devine

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For: **Analytical Method Comprising Addition in Two or More Positions and a Device and Test Kit Therefor**

REPLY BRIEF UNDER 37 CFR §41.41

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief in submitted in response to the Examiner's Answer mailed December 17, 2004. The comments herein are directed to the Examiner's response to Appellants' appeal arguments.

Claims 1 and 18

According to independent method claim 1, flow is initiated in the flow matrix by adding liquid to each liquid application zone in such a way that $liquid_{n+1}$, added to the application zone LZ_{n+1}, contacts the flow matrix substantially simultaneously with and is transported through the matrix immediately after $liquid_n$ added to the nearest downstream liquid application zone LZ_n. Similarly, the device defined by independent claim 18 is adapted, when flow is initiated by adding liquid to each liquid application zone in such a way that $liquid_{n+1}$ added to the application zone LZ_{n+1}, contacts the flow matrix substantially

simultaneously with and is transported through the matrix immediately after $liquid_n$, added to the nearest downstream application zone LZ_n.

At page 10, beginning at line 5 of the Examiner's Answer, the Examiner asserts that the claims do not make clear what liquid may be added to the various zones, whereby this liquid could be buffer or substrate solution, in which case, after the complex of Dafforn reaches the detection zone, the bound complex acts on any substrate solution that subsequently enters the detection zone, resulting in a color change. Appellants assume that the Examiner is referring to the embodiment disclosed at column 24 of Dafforn et al, but believe that the Examiner mischaracterizes the teachings of Dafforn et al. That is, Dafforn et al disclose that sample is added at a first opening and a developer solution containing enzyme substrate is added at the second opening and, during subsequent incubation, HCG binds to the conjugate, the complex is carried *by the moving developer* to the detection zone where it binds, and the bound complex acts on the substrate to produce color at the detection zone when HCG is present in the sample (column 24, lines 29-37). As Dafforn et al teach that the developer solution contains enzyme substrate and the developer solution carries the HCG-conjugate complex prior to arrival in the detection zone, it is clear that Dafforn et al do not teach simultaneously application of developer and sample with sequential transport of developer and sample. To the contrary, Dafforn et al specifically teach that the developer, including the enzyme substrate, mixes with the HCG-conjugate complex prior to arrival in the detection zone. Thus, Dafforn et al do not teach the limitations of claim 1 or claim 18 requiring simultaneous application and sequential transport of liquids in adjacent liquid application zones.

At page 10, beginning at line 19 of the Examiner's Answer, and again at page 16, beginning at line 9, the Examiner asserts that there is no recitation excluding any mixing or carrying or that all reagents and sample reagents reach a detection zone in the exact same

order without any mixing or carrying. Appellants assert that the Examiner's statement is in error. That is, Appellants submit that the recitation in the present claims that liquid $_{n+1}$ added to the application zone LZ_{n+1} contacts the flow matrix substantially simultaneous with and is transported through the matrix *immediately after* $liquid_n$ added to the nearest downstream application zone LZ_n in fact means that the liquid supplied to the respective liquid application zones reach the detection zone in the exact same order, without any mixing or carrying. The Examiner provides no reasoning as to why the phrase "immediately after" means simultaneously and does not exclude mixing or carrying. The Examiner simply disregards the ordinary meaning of this phrase as is illustrated in the specific teachings in the present specification.

At page 11, beginning at line 5 of the Examiner's Answer, the Examiner asserts that if the developer/substrate of Dafforn et al and complex mixed prior to the detection zone, a color would appear prior to the detection zone which would be contrary to the teachings of Dafforn et al. However, the Examiner's assertion disregards the specific teachings of Dafforn et al that the HCG-conjugate complex is "carried by the moving developer to the detection zone" and that the developer solution contains enzyme substrate. While Dafforn et al do not specifically disclose if color appears prior to the detection zone, Dafforn et al surely do specifically disclose that the developer solution contains the enzyme substrate and that the developer solution carries the HCG-conjugate complex to the detection zone (column 24, lines 29-37).

At page 11, beginning at line 15 of the Examiner's Answer, the Examiner asserts that claims 1 and 18 are missing an essential element for achieving sequential flow without mixing the fluids between the two application zones, namely zone spacers. Appellants submit however that there is no necessity for the independent claims to recite the presence of zone spacers as each of these claims includes the limitation that $liquid_{n+1}$ added to the

application zone LZ_{n+1}, contacts the flow matrix substantially simultaneously with and is transported through the matrix immediately after $liquid_n$ added to the nearest downstream application zone LZ_n. The Examiner has not provided any reason as to why a specific means for providing the sequential flow required by these claims is necessary. Further, the present specification clearly indicates at page 6 that zone spacers are one manner in which to provide the sequential flow, and the present specification clearly describes additional embodiments wherein zone spacers are not required (see, for example, page 6, lines 20-24). Thus, the Examiner's assertion that the claims must recite zone spacers is in error.

Accordingly, the method of claim 1 and the device of claim 18 are not taught by Dafforn et al.

Claims 3 and 20

Claims 3 and 20 relate to the embodiment of the present method and device wherein n" = n', i.e., the application zone for analytically detectable Reactant*, and the application zone for sample are the same. At page 12, beginning at line 10 of the Examiner's Answer, the Examiner asserts that Dafforn et al teach an application zone wherein labeled reagent, namely enzyme conjugate, and sample are provided in the same application area and developer liquid reagent, with enzyme substrate, is provided in the application area upstream of the sample. Thus, contrary to the position discussed above wherein the Examiner asserts that the enzyme substrate in the developer solution produces color, the Examiner now appears to assert that the enzyme conjugate is an analytically detectable Reactant*. Appellants believe that it is clear from the teachings of Dafforn et al that the developer solution containing the enzyme substrate produces color at the detection zone. Dafforn et al do not disclose that the predeposited enzyme conjugate is an analytically detectable Reactant*; to the contrary,

Dafforn et al teach that the added developer solution contains the color-producing enzyme substrate. Thus, Dafforn et al do not teach the limitations of present claims 3 and 20.

Claims 10 and 24

Claims 10 and 24 are directed to the embodiment of the present method and device wherein the liquid application zones have zone spacers between each other. Claims 1 and 18, from which these claims respectively depend, recite that the liquid application zones are elements of the flow matrix. The Examiner has asserted that the housing portions between sample application wells of Dafforn et al are zone spacers as presently claimed. At page 13, beginning at line 8 of the Examiner's Answer, the Examiner asserts that the features upon which Appellant rely, that the zone spacers are in the flow matrix rather than in a housing well, are not recited in the rejected claims. Appellants submit that the Examiner's position is in error as claims 10 and 24 recite that the liquid application zones LZ have zone spacers between each other, and the claims from which these claims depend recite that the liquid application zones are elements of the flow matrix. Thus, the zone spacers will necessarily be positioned in the flow matrix and the housing wells taught by Dafforn et al are not zoned spacers as presently claimed. Therefore, Dafforn et al do not teach the method and device of claims 10 and 24.

Claims 4 and 21

At page 13 of the Examiner's Answer, the Examiner asserts that the Dafforn et al teach the limitation of claim 21, and at page 15, beginning at line 9 of the Examiner's Answer, the Examiner asserts that Dafforn et al teach the limitation of claim 4, namely that the analytically detectable reactant is pre-deposited in its application zone. Appellants submit that the Examiner is in error. That is, as discussed above, Dafforn et al teach that the

developer solution, including the enzyme substrate, is applied to the second opening, and that the enzyme conjugate, not an analytically detectable reactant, is predeposited in the device (column 24, lines 29-37). Thus, claims 4 and 21 are independently patentable from the teachings of Dafforn et al.

Claims 2 and 19

At page 14, beginning at line 11 of the Examiner's Answer, the Examiner asserts that claims 2 and 19, requiring sequential transport of analyte and Reactant*, are obvious over Dafforn et al. The Examiner asserts that while Dafforn et al teach that when analytically detectable reactant is added upstream of sample, the liquid reagent usually is added following the addition of sample, Dafforn et al also teach the addition of liquid reagent simultaneously, referring to column 24. The Examiner's reasoning is based on a selection of isolated teachings of Dafforn et al and combining those teachings along the lines of the present invention, without any specific teaching, suggestion or motivation of such a combination provided by Dafforn et al. That is, the only teachings which Appellants find by Dafforn et al relating to the addition of liquid reagents simultaneously is at column 24. Dafforn et al provide no teaching or suggestion for combining selected portions of other methodologies with selected portions of the embodiment described at column 24, particularly to result in a method or device as defined by the present claims. While Appellants agree that a reference is not limited to its preferred embodiments, the mere fact that prior art could be modified to result in the claimed invention would not have made the modification obvious unless the prior art suggested the desirability of the modification, *In re Mills*, 16 U.S.P.Q. 1430 (Fed. Cir. 1990); *In re Fritch*, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992). Dafforn et al provide no suggestion of the desirability of the modifications made by the Examiner to arrive at the claimed methods and devices.

At the last two lines of page 14 of the Examiner's Answer, the Examiner states that Dafforn et al does not teach mixing. The Examiner's statement is clearly contrary to the specific teachings of Dafforn et al at column 24, lines 32-35 which teach that the HCG-conjugate complex is carried by the moving developer to the detection zone.

Thus, the method and device of claims 2 and 19 are nonobvious and independently patentable over Dafforn et al.

Claims 34 and 35

Finally, at page 18, beginning at line 8 of the Examiner's Answer, the Examiner asserts that he has not relied upon Goerlach-Graw et al for teaching a single flow matrix having liquid application zones in series but has relied upon Dafforn et al for these teachings. However, the zone spacers to which claims 34 and 35 are directed are for the purpose of dividing liquid application zones which are in series in a single flow matrix. The fact that Goerlach-Graw et al teach individual test strips, but fail to teach a single flow matrix having a plurality of liquid application zones in series therein demonstrates the lack of teaching, suggestion or motivation for combining the features of Goerlach-Graw et al with the device of Dafforn et al to reject claims 34 and 35. Again, the mere fact that the prior art can be modified to result in the claimed invention does not make the modification obvious unless the prior art suggests the desirability of the modification, *In re Mills, supra.*; *In re Fritch, supra.* Both Dafforn et al and Goerlach-Graw et al lack the requisite suggestion of desirability. Thus, claims 34 and 35 are nonobvious over Dafforn et al in view of Goerlach-Graw et al.

Conclusion

For the reasons set forth in detail above and in the Appeal Brief, Appellants submit that the methods and devices defined by claims 1-4 and 6-35 are neither anticipated by nor

rendered obvious over Dafforn et al, alone or in combination with the secondary references cited by the Examiner. Accordingly, the rejections of the claims under 35 U.S.C. §§102 and 103 should be reversed. Favorable action by the Board is respectfully requested.

Respectfully submitted,

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